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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,078	03/22/2004	Lakshmi Vijay	U 015092-8	1385
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William R. Evans Ladas & Parry 26 West 61 Street New York, NY 10023		EXAMINER FERNANDEZ, SUSAN EMILY		
		ART UNIT PAPER NUMBER 1651		
DATE MAILED: 12/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/806,078

Applicant(s)

VIJAY ET AL.

Examiner

Susan E. Fernandez

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 1-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 9/30/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment filed November 21, 2005, has been received and entered. Claims 1-16 are pending.

Election/Restrictions

Applicant's election of Group II, claims 7-16, in the reply filed on November 21, 2005, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 7-16 are examined on the merits to the extent they read on the elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 11, 12, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 8 and 11 are rendered indefinite by the phrase "...0.01% to 1.0% aqueous solution." The phrase is confusing because it is not clear whether the percentages refer to the percentages of bivittoside D present in the aqueous solution.

Claims 12 and 16 are confusing since it is unclear how a composition can be in multiple forms at once (cream AND jelly AND free-flowing powder...). For examination purposes, the forms recited in claims 12 and 16 will be read as compositions in the form of a cream, jelly, free-flowing powder, solution, suspension, OR alcoholic extract.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 9, 10, 12, 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kitagawa et al. (Chem. Pharm. Bull., 1989, 37(1): 61-67).

Kitagawa et al. discloses bivittoside D isolated from *Bohadschia bivittata* (abstract). To obtain bivittoside D, extractions and purification by column chromatography were performed, where the final purification step involved column chromatography with a CHCl₃-MeOH-H₂O lower phase (page 65, first column, "Isolation of Bivittosides A (6), B (8), C (9), and D (10)"). Thus, bivittoside D is obtained in a pure form as required by instant claim 10, in a composition in the form of a solution, suspension or alcoholic extract as required by instant claims 12 and 16,

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and in a composition comprising one or more conventional additives as required by instant claim 13. Finally, bivittoside D inhibits the growth of various fungi, including *Candida albicans* (page 64, second column, second paragraph, and Table II).

Though bivittoside D is not isolated from *Bohadschia vitiensis* in Kitagawa et al., independent claims 9, 13, and 15 and dependent claims 10 and 16 under examination are taught by the reference since bivittoside D is the same regardless of its source. Note that claims 9-11, and 13-16 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. "[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the

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claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Additionally, although the reference does not specifically teach that the composition is effective as a spermicidal agent, the compositions are the same, thus the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new. As pointed out in MPEP §2112, “the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable”. Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Thus, a holding of anticipation is clearly required.

Claims 7, 9, 10, and 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorshkova et al. (Toxicon, 1989, 27(8): 927-936).

Gorshkova et al. discloses a use of bohadschioside A, which is also known in the art as bivittoside D. See page 928, first paragraph under "Results." Bivittoside D is purified, thus it is in its pure form as required by claim 10 under examination. Bivittoside D combined with solutions of Tris-HCl is used in various experiments, where this glycoside is in concentrations of 5×10^{-4} M (page 928, fourth paragraph) or as high as 10^{-3} M (page 928, fifth paragraph). Thus, bivittoside D is in a composition in the form of a solution or suspension as required by instant claims 12 and 16, and in a composition comprising one or more conventional additives as required by instant claim 13. Furthermore, since the molecular weight of bivittoside D is about 1426 g/mol (formula of bivittoside D is $C_{67}H_{110}O_{32}$), in the experiments indicated above, bivittoside D is in concentrations of about 0.713 mg/ml or as high as 1.43 mg/ml. Therefore, bivittoside D is in concentrations within the range recited in instant claim 14.

Though bivittoside D is not isolated from *Bohadschia vitiensis* in Gorshkova et al., independent claims 9, 13, and 15 and dependent claims 10, 14, and 16 under examination are taught by the reference since bivittoside D is the same regardless of its source. Note that claims 9-11, and 13-16 are product-by-process claims. M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the

prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. “[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability of the product claimed and not of the recited process steps which must be established. We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith.” *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Additionally, although the reference does not specifically teach that the composition is effective as a spermicidal agent or fungicidal composition, the compositions are the same, thus the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for

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the prior art's functioning, does not render the old composition patentably new. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable". Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Thus, a holding of anticipation is clearly required.

Claims 7, 9, 10, 12, 13, 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuznetsova et al. (Comp. Biochem. Physiol., 1982, 73C(1): 41-43) taken in light of Antonov et al. (Khimiya Prirodnikh Soedinenii, 1986, 3: 379-80 and CAPLUS English abstract).

Kuznetsova et al. discloses glycoside fractions isolated from various sources by aqueous-alcoholic extractions (page 41, first column, "Isolation of glycoside fractions of Holothuria"), thus the glycosides are in their pure form and are alcoholic extracts. Furthermore, bivittosides were obtained from *Bohadschia vitiensis* (page 42, Tables 1 and 2). Note that Antonov et al. discloses that bivittoside D is found in *B. vitiensis* (CAPLUS English abstract), thus the bivittosides obtained from *B. vitiensis* disclosed in Kuznetsova et al. inherently comprise of bivittoside D. The bivittosides from *B. vitiensis*, which are in one of the glycoside fractions studied by Kuznetsova et al., may be in aqueous or aqueous-alcoholic solutions (page 41, second column, first and second paragraphs). Thus, the bivittosides from *B. vitiensis* are in a

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composition comprising one or more pharmaceutically acceptable additives (water) as required by instant claim 7, which is a solution, suspension or an alcoholic extract as required by instant claims 12 and 16, and comprising one or more conventional additives (water) as required by instant claim 13. Finally, the glycoside fraction comprising of these bivittosides has an inhibitory effect on *Candida albicans* (page 42, Table 2).

Although the reference does not specifically teach that the composition is effective as a spermicidal agent, the compositions are the same, thus the claimed function must be inherent to the reference composition. The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new. As pointed out in MPEP §2112, "the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable". Furthermore, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Thus, a holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-13, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuznetsova et al. in light of Antonov et al.

As discussed above, Kuznetsova et al. in light of Antonov et al. anticipates claims 7, 9, 10, 12, 13, 15, and 16. However, these references do not expressly disclose the concentrations of bivittoside D in aqueous solution as recited in claims 8 and 11 under examination.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have varied the concentration of bivittoside D in aqueous solution to other concentrations, including those recited in instant claims 8 and 11. The selection of specific suitable concentrations in aqueous solution, including those claimed, clearly would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly in view of the prior art's disclosure that different concentrations were prepared (page 41, column 2, first paragraph).

Additionally, Kuznetsova et al. and Antonov et al. do not expressly disclose the bivittosides in compositions in all the forms recited in claims 12 and 16 under examination.

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At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have prepared the bivittosides obtained from *B. vitiensis* in various forms. One of ordinary skill in the art would have been motivated to do this since one of ordinary skill would have expected that the fungicidal activity of the bivittosides of Kuznetsova et al. would have been suitably applied in the form of the claimed cream, jelly, or free-flowing powder since one of ordinary skill would have been motivated to have placed a known fungicide in a topically applicable form.

Thus, a holding of obviousness is clearly required.

Claims 7, 9, 10, 12, 13, 15, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kitagawa et al.

As discussed above, Kitagawa et al. anticipates claims 7, 9, 10, 12, 13, 15, and 16. However, Kitagawa et al. does not expressly disclose the bivittoside D-containing compositions in all the forms recited in claims 12 and 16 under examination.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have prepared the bivittoside D-containing compositions in various forms. One of ordinary skill in the art would have been motivated to do this since one of ordinary skill would have expected that the fungicidal activity of the bivittosides D-containing composition of Kitagawa et al. would have been suitably applied in the form of the claimed cream, jelly, or free-flowing powder since one of ordinary skill would have been motivated to have placed a known fungicide in a topically applicable form. Thus, a holding of obviousness is clearly required.

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Claims 7, 9, 10, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorshkova et al. in light of Kitagawa et al.

As discussed above, Gorshkova et al. anticipates claims 7, 9, 10, and 12-16. The bittovide D-containing compositions disclosed by Gorshkova et al. are inherently fungicidal since Kitagawa et al. discloses that bivittoside D inhibits the growth of various fungi, including *Candida albicans* (page 64, second column, second paragraph, and Table II).

Gorshkova et al. does not expressly disclose the bivittoside D-containing compositions in all the forms recited in claims 12 and 16 under examination.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to have prepared the bivittoside D-containing compositions in various forms. One of ordinary skill in the art would have been motivated to do this since one of ordinary skill would have expected that the fungicidal activity of the bivittosides D-containing composition of Gorshkova et al. would have been suitably applied in the form of the claimed cream, jelly, or free-flowing powder since one of ordinary skill would have been motivated to have placed a known fungicide in a topically applicable form. Thus, a holding of obviousness is clearly required.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444.

The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan E. Fernandez
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Art Unit 1651

sef



FRANCISCO PRATS
PRIMARY EXAMINER